



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0834. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Information Sharing Among Constituent Part Applicants for Combination Products--21 CFR 4.103

OMB Control Number 0910-0834--Extension

This information collection request applies to "constituent part applicants" as defined under 21 CFR 4.101 (i.e., any person holding an application under which a constituent part (drug, device, or biological product) of a combination product received marketing authorization if the other constituent part(s) received marketing authorization under an application held by a different person). Under this collection, constituent part applicants must share safety information they receive related to certain events with the other constituent part applicant(s) and maintain associated records.<sup>1</sup>

In the *Federal Register* of April 30, 2020 (85 FR 23971), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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<sup>1</sup> The Postmarketing Safety Reporting (PMSR) information collections for drugs, biological products, and devices found in §§ 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20 (21 CFR 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20) have already been approved and are in effect or their extension is being sought separately as required, including with respect to burden for combination products (reflected in the authorization for OMB control number 0910-0834, but, therefore, not addressed in this extension request). The pertinent PMSR information collection provisions for § 314.80(c) and (e), as well as for § 314.81(b) are approved under OMB control numbers 0910-0001, 0910-0230, and 0910-0291. The information collection provisions for §§ 600.80 and 600.81 are approved under OMB control number 0910-0308. Those for § 606.170 are approved under OMB control number 0910-0116. Those for § 606.171 are approved under OMB control number 0910-0458. The information collection provisions for §§ 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910-0291 and 0910-0437. The information collection provisions for §§ 806.10 and 806.20 are approved under OMB control number 0910-0359.

FDA estimates the burden of this collection of information as follows:

Table1.--Estimated Annual Third-Party Disclosure and Recordkeeping Burden

21 CFR Section; Activity	No. of Respondents/R ecordkeepers	No. of Disclosures/Records per Respondent/Recordkeeper	Total Annual Disclosures/R ecords	Average Burden per Disclosure/Rec ordkeeping	Total Hours
4.103, Sharing information with other constituent part applicants	33	18	594	0.35 (21 minutes)	208
4.103(b) and 4.105(a)(2), Records of information shared by constituent part applicants	33	18	594	0.1 (6 minutes)	59
Total					267

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We note in this regard that FDA extended the compliance date for 21 CFR part 4, subpart B, until July 2020 for most combination products, and until January 2021 for the remainder, in response to stakeholder feedback, to ensure that Combination Product Applicants have sufficient time to update reporting and recordkeeping systems and procedures.<sup>2</sup> Consequently, entities subject to this rule have not yet had to comply with this information request.

Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-17041 Filed: 8/4/2020 8:45 am; Publication Date: 8/5/2020]

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<sup>2</sup> See Compliance Policy for Combination Product Postmarketing Safety Reporting (April 2019) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting>).